(II) REMARKS:

Detailed discussion and comparison of prior arts and the present application in responding to the comments from the Examiner.

There are several fundamental differences between the prior art and the present application:

(a) The laser-tissue interaction area cited in prior arts patented by Lin (USPN 5,520,679) , Smith (USPN 5,490,849), and Ruiz (USPN 5,533,997) are all within the central portion of the cornea, whereas the laser ablation proposed by the present application is <u>outside</u> the corneal limbus area.

We have also amended our main independent Claim to include that the laser ablation area is <u>the sclera tissue outside the limbus.</u>

(b) In the prior arts, the laser is used to change corneal curvature (Lin,Smith, Ruiz) or thermally shrink the corneal shape (Sand in USPN. 5,484,432) such that patients' vision is corrected. These prior arts methods are ONLY good for myopia and hyperopia corrections and CAN NOT correct presbyopia. The presbyopia correction proposed in the present application, on the contrary, does not change the corneal central curvature but only increase the accommodation of the lens by removing portion of the sclera tissue outside the limbus.

(c) Presbyopia correction by a laser is a new procedure which is TOTALLY different from the teaching of prior arts using lasers for corneal "reshaping". Presbyopia correction also requires patient's far view unchanged (or without reshaping of the cornea) and only improve the near-view by lens accommodation.

(d) Furthermore, the present application uses a "cold" laser to remove sclera tissue (outside the limbus area) versus a "thermal" lasers in Sand's patent (Pat. No. 5,484,432) to shrink the corneal shape (inside the limbus area). The cold laser of the present application has a wavelength range of (0.15-0.36) microns and (2.6-3.2) microns which are also different from that of the "thermal" laser range of (1.80-2.55) microns proposed by Sand.

(e) The UV laser wavelength at 193nm proposed in the prior art of Lin etc and the IR wavelength of Lin and Bille are within the range of (0.15-0.36) and (2.7-3.2) microns proposed in the present application. However, the teaching of the prior art is limited to the ablation of the corneal central surface. None of the prior art teachings in corneal reshaping can be used for the

correction of presbyopia without using the INNOVATIVE teachings proposed in the present application. In fact, corneal reshaping taught by the prior art MUST be avoided in the new procedure of presbyopia correction for patients to see near and and far (or keep far view remains as good as prior to the surgery).

(f) The "presbyopia" correction proposed by Ruitz (US Pat. 5,533,997) using an excimer (ArF at 193 nm) laser required the corneal surface to be reshaped to "multifocal" for a presbyopia patient to see near and far. However, Ruitz's "presbyopia" correction is fundamentally different from that of the present application and should not be called "presbyopia" correction under the definition of lens accommodation per cited in the present application. The generallly accepted definition for presbyopia correction is to increase patient's accommodation rather than reshaping the cornea into "multifocal".

(g) The technique used in the prior art of **Bille (USPN 4,907,586)** are specified as follows:

(1) quasi-continuous laser having pulse duration less than 10 picoseconds and focused spot less than 10 micron diameter (claims 1,10, 23, 41 and 56); (2) the laser is confined to the interior of a selected tissue to correct myopia, hyperopia or astigmatism (claims 11, 14. 25, 29, 30, 33, 54 60 and 63); (3) the laser is focused into the lens of an eye to prevent presbyopia (claim 26, 31, 50, 55 and 61); (4) laser create a cavity within the corneal stroma to change its visco-elastic properties (claims 41, 52 and 54).

In comparison, the laser parameters defined in the present application and its applications are fundamentally different from the above prior art per described in the present Claims as follows: (i) laser spot sizes are (0.1-0.5)mm which is much larger than Bille's 10 micron (or 0.01mm) and pulse duration of less than about 200 microseconds, which is about 1,000,000 times longer than Bille's picosecond requirement; (ii) the laser is used to ablate the sclera tissue outside the limbus for

presbyopia correction, rather than into the lens of the eye proposed by Bille; (iii) the effects of the laser is to remove portion of the sclera tissue and increase the accommodation of the lens, rather than change the corneal visco-elastic properties or cause the change of corneal curvature for myopia or hyperopia correction proposed by Bille. The prior art of Bille proposed a picosecond laser tightly focused (spot size of less than 0.01mm) into the lens of the eye for presbyopia correction. These are fundamentally different from what are proposed by the present application: a microsecond laser having spot size about (0.1-0.5)mm and applied onto the sclera tissue (rather than into the corneal lens). No clinical results or testing have been reported using Bille's technique for the correction of presbyopia.

Conclusion of Remarks:

In view of the above discussion, the present inventor believes that it would be non-obvious to a normal skill person to utilize the teachings provided by the prior arts of Ruiz,Lin, Smith, Bille and Sand etc to achieve the "presbyopia" correction (defined by patient's accommodation, rather than the muti-focal defined by Ruiz) proposed in the present application. In fact, the concept of laser scleral ablation outside the limbus area (rather than reshaping the central portion of the cornea) is innovative and has been clinically tested based the proposed techniques in the present application. The present inventor has used these technique to treat over 100 cases of presbyopia patients with very good results and almost no regression after longer than 17 months follow up. These clinical results based on the teaching proposed in the present application have not been explored by any of the prior arts.

(III) Version with marking to show changes made

Title:

TREATMENT OF PRESBYOPIA AND OTHER EYE DISORDERS USING A (amended)<u>DUAL-LASER SCANNING</u> SYSTEM

Claims:

notes: Claims 9, 10, 12-20, 22-24 are non-elected, and Claims 1-8, 11 and 21 are amended (indicated by underlines).

1. A laser beam ophthalmological surgery method for treating presbyopic in a patient's eye by ablating the sclera comprising the steps of :

selecting a pulsed ablation laser having a pulsed output beam of predetermined wavelength (delete)<u>and an energy per pulse of between 0.1 - 5 mJ on the surface of the cornea</u>;

selecting a beam spot controller mechanism for reducing and focusing said selected ablative laser's output beam onto a predetermined spot size on the surface of the cornea;

selecting a scanning mechanism for scanning said ablative laser output beam;

coupling said ablative laser beam to a scanning device for

scanning said ablative laser over a predetermined area of the corneal sclera; and

controlling said scanning mechanism to deliver said ablative laser beam in a predetermined pattern in said predetermined area onto the surface of the cornea to photoablate the sclera (adding)<u>tissue outside the limbus</u>, whereby a presbyopic patient's vision is corrected by expansion of the sclera.

2. A laser beam ophthalmological surgery method for treating presbyopic in a patient's eye by ablating the sclera in accordance with claim 1 in which the step of selecting a pulsed ablation laser includes selecting a pulsed ablative laser having a predetermined wavelength between 0.15 - 0.32 microns.

3. A laser beam ophthalmological surgery method for treating presbyopic in a patient's eye by ablating the sclera in accordance with claim 1 in which the step of selecting a pulsed ablation laser includes selecting a pulsed ablative laser having a wavelength between 2.6 and 3.2 microns.

4. A laser beam ophthalmological surgery method for treating presbyopic in a patient's eye by ablating the sclera in accordance with claim 1 in which the step of selecting a pulsed ablation laser includes selecting a (delete) <u>Q-switched</u> solid state laser. (Delete) <u>having a pulse duration shorter than 200 nanoseconds.</u>

5. A laser beam ophthalmological surgery method for treating presbyopic in a patient's eye by ablating the sclera in accordance with claim 1 in which the step of selecting a pulsed ablation laser includes selecting a pulsed gas laser having a pulse duration shorter than 200 nanoseconds.

6. A laser beam ophthalmological surgery method for treating presbyopic in a patient's eye by ablating the sclera in accordance with claim 1 in which said the step of selecting a beam spot controller includes selecting a pulsed ablative laser having a focusing lens with focal length of between 10 and 100 cm selected to obtain a predetermined laser beam spot size having a

diameter of between 0.1 and 0.8 mm on the corneal surface.

7. A laser beam ophthalmological surgery method for treating presbyopic in a patient's eye by (delete)6g ablating the sclera in accordance with claim 1 in which the step of selecting a beam spot controller includes selecting beam spot controller having a focusing lens with cylinder focal length of between 10 and 100 cm to obtain a laser beam spot having a line size of about 0.1-0.8 mm x 3-5 mm on the corneal surface.

8. A laser beam ophthalmological surgery method for treating presbyopic in a patient's eye by ablating the sclera in accordance with claim 1 in which the step of selecting a scanning mechanism includes selecting a scanning mechanism having a pair of reflecting mirrors mounted to a galvanometer scanning mechanism for controlling said laser output beam into a predetermined (delete)overlapping pattern.

NOTE: Claims 9, 10, 12-20, 22-24 are non-elected, and Claims 11 and 21 are amemded (indicated by underlines)

9. A laser beam ophthalmological surgery method for treating presbyopic in a patient's eye by ablating the sclera in accordance with claim 8 in which the step of selecting said scanning mechanism includes selecting a scanning mechanism having an overlapping pattern overlapping from 20 to 80% within the selected area of the sclera.

10. A laser beam ophthalmological surgery method for treating presbyopic in a patient's eye by ablating the sclera in accordance with claim 1 including the steps of:

selecting a coagulative laser having a pulsed output beam of predetermined wavelength; and

directing said selected coagulative laser onto those areas of the sclera photoablated with the selected pulsed ablation laser.

11. A laser beam ophthalmological surgery method for treating

presbyopic in a patient's eye by ablating the sclera in accordance with claim 10 (add) in which the predetermined pattern is generated by including the steps of:

selecting a metal mask having at least on (corrected to one) slit therein; and

positioning the selected mask over the cornea surface for scanning the ablation laser thereover for controlling the ablation slit pattern on the sclera (add) tissue outside the limbus.

12. A laser beam ophthalmological surgery method for treating presbyopic in a patient's eye by coagulating sclera tissue ablated with an ablating laser beam to prevent bleeding in the tissue including the steps of:

selecting an ablation laser having an output beam of predetermined wavelength for ablating the surface of the cornea;

ablating a predetermined area of the cornea sclera with the output beam from said ablation laser;

selecting a coagulative laser having an pulsed output beam of predetermined wavelength having an average power of between 20-3000 mW on the surface of the cornea;

selecting a beam spot controller mechanism for reducing and focusing said coagulative laser beam to a predetermined spot size on the corneal surface;

selecting a scanner for scanning said coagulative laser output beam;

coupling said coagulative laser beam onto a scanner for scanning said coagulative laser beam over a predetermined area of the corneal sclera which has been ablated by said ablation laser;

controlling the scanner to deliver said coagulative laser output beam in a predetermined pattern onto a plurality of positions on the corneal surface to coagulate the ablated areas of the sclera, whereby bleeding in said ablated tissue is reduced by the said coagulation laser beam.

13. A laser beam ophthalmological surgery method for treating presbyopic in a patient's eye by coagulating sclera tissue ablated with an ablating laser beam to prevent bleeding in

the tissue in accordance with claim 12 in which said predetermined wavelength is between 0.5 and 3.2 microns.

14. A laser beam ophthalmological surgery method for treating presbyopic in a patient's eye by coagulating sclera tissue ablated with an ablating laser beam to prevent bleeding in the tissue in accordance with claim 12 in which said predetermined wavelength is between 5.5-10.6 microns.

15. A laser beam ophthalmological surgery method for treating presbyopic in a patient's eye by coagulating sclera tissue ablated with an ablating laser beam to prevent bleeding in the tissue in accordance with claim 12 in which said coagulative laser is a continuous wave laser.

16. A laser beam ophthalmological surgery method for treating presbyopic in a patient's eye by coagulating sclera tissue ablated with an ablating laser beam to prevent bleeding in the tissue in accordance with claim 12 in which said selected coagulative laser is a long pulse laser having a pulse duration longer than 200 nanoseconds.

17. A laser beam ophthalmological surgery method for treating presbyopic in a patient's eye by coagulating sclera tissue ablated with an ablating laser beam to prevent bleeding in the tissue in accordance with claim 12 in which said step of selecting a beam spot controller includes selecting a focusing lens having a focal length of between 10 and 100 cm. to obtain a predetermined laser beam spot size having a diameter between 0.2-2.0 mm on the corneal surface.

18. A laser beam ophthalmological surgery method for treating presbyopic in a patient's eye by coagulating sclera tissue ablated with an ablating laser beam to prevent bleeding in the tissue in accordance with claim 12 in which said selecting beam spot controller includes a focusing lens having a focal length of between 10 and 100 cm selected to obtain a predetermined laser beam spot having a line size of about 0.2-2.0 x 3-5 mm on

the corneal surface.

19. A laser beam ophthalmological surgery method for treating presbyopic in a patient's eye by coagulating sclera tissue ablated with an ablating laser beam to prevent bleeding in the tissue in accordance with claim 12 in which the step of selecting a scanning mechanism includes selecting a scanning mechanism having a pair of reflecting mirrors mounted to a galvanometer scanner for controlling said coagulative laser output beam into an overlapping pattern following said ablative laser output beam ablating surface tissue on the corneal surface.

20. A laser beam ophthalmological surgery method for treating presbyopic in a patient's eye by coagulating sclera tissue ablated with an ablating laser beam to prevent bleeding in the tissue in accordance with claim 19 in which said overlapping pattern includes an overlap of between 20 and 80% in a pattern defined on the corneal surface by said ablative laser.

21. A laser beam ophthalmological surgery method for treating presbyopic in a patient's eye by (delete)coagulating sclera tissue ablated with an ablating laser beam (delete) to prevent bleeding in the tissue in accordance with claim 12 (changed to Claim 1) in which said ablative laser (delete) has a wavelength between 0.5-3.2 microns and a pulse width shorter than 200 nanoseconds is delivered to the surface of the cornea by an optical fiber.

22. A laser beam ophthalmological surgery method for treating presbyopic in a patient's eye by coagulating sclera tissue ablated with an ablating laser beam to prevent bleeding in the tissue in accordance with claim 12 in which said selected coagulative laser has a wavelength of between 0.5-10.6 microns, and a pulse width longer than 200 nanoseconds delivered to the surface of the cornea by an optical fiber to prevent tissue bleeding.

23. A laser beam ophthalmological surgery method for treating presbyopic in a patient's eye by coagulating sclera

tissue expanded by a knife to prevent bleeding in the tissue including the steps of:

cutting a predetermined area of the cornea sclera with a knife;

selecting a coagulative laser having an pulsed output beam of predetermined wavelength having an average power of between 20-3000 mW on the surface of the cornea;

selecting a beam spot controller mechanism for reducing and focusing said coagulative laser beam to a predetermined spot size on the corneal surface;

selecting a scanner for scanning said coagulative laser output beam;

coupling said coagulative laser beam onto a scanner for scanning said coagulative laser beam over a predetermined area of the corneal sclera which has been cut with said knife;

controlling the scanner to deliver said coagulative laser output beam in a predetermined pattern onto a plurality of positions on the corneal surface to coagulate the cut areas of the sclera, whereby bleeding in said cut tissue is reduced by the said coagulation laser beam.

24. A laser beam ophthalmological surgery method for treating presbyopic in a patient's eye by coagulating sclera tissue expanded by a knife to prevent bleeding in the tissue in accordance with claim 23 in which the selected coagulative laser has a wavelength of between 0.5 and 10.6 microns and a pulse width longer than 200 nanoseconds.

ABSTRACT OF THE DISCLOSURE

Presbyopia is treated by a method which uses ablative lasers to ablate the sclera tissue and increase the accommodation of the ciliary body. Tissue bleeding is prevented by a (amended) dual-beam system which consists of ablative and coagulative lasers. The preferred embodiments of the present invention include a short pulse ablative laser (pulse duration less than 200 nanoseconds) having a wavelength of between 0.15 and 3.2 microns and a long pulse (longer than 200 nanoseconds) coagulative laser having a wavelength range of between 0.5 and 10.6 microns. A scanning system is proposed to perform various patterns on the sclera area

of the cornea to treat presbyopia and to prevent other eye disorder such as glaucoma. Laser parameters are determined for accurate sclera expansion.